Complete Summary

GUIDELINE TITLE

American Society of Clinical Oncology treatment of unresectable non-small-cell lung cancer guideline: update 2003.

BIBLIOGRAPHIC SOURCE(S)

Pfister DG, Johnson DH, Azzoli CG, Sause W, Smith TJ, Baker S Jr, Olak J, Stover D, Strawn JR, Turrisi AT, Somerfield MR. American Society of Clinical Oncology treatment of unresectable non-small-cell lung cancer guideline: update 2003. J Clin Oncol 2004 Jan 15;22(2):330-53. [293 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Unresectable clinical (as opposed to pathologic) stage III and stage IV non-small-cell lung cancer

GUIDELINE CATEGORY

Diagnosis
Management
Prevention
Treatment

CLINICAL SPECIALTY

Oncology
Pulmonary Medicine
Radiology
Thoracic Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To update the 1997 clinical practice guidelines for the diagnostic evaluation, treatment, and follow-up care of patients with unresectable non-small-cell lung cancer

TARGET POPULATION

Adults with unresectable non-small-cell lung cancer who are not participating in clinical trials

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Chest x-ray and computed tomography (CT) scan with infusion of contrast material
2. Fluorodeoxyglucose positron emission tomography (FDG-PET) scan
3. Biopsy
4. Bone scan
5. Head CT or magnetic resonance imaging (MRI) brain imaging
6. Ultrasonography
7. Adrenal and/or liver biopsy, if applicable

Treatment

1. Chemotherapy
    - Platinum-based and non-platinum-based combination regimens
    - Docetaxel
    - Gefitinib
    - Investigational agents for selected patients
2. Radiotherapy
3. Surgery
4. Resection followed by whole-brain radiation therapy

Management

1. Follow-up history and physical examination
2. Other diagnostic studies as indicated

Prevention

1. Smoking cessation
2. Avoidance of occupational and environmental exposure to carcinogens

Note: Chemopreventive agents were considered but are not recommended.

MAJOR OUTCOMES CONSIDERED

- Survival rates (disease-free, overall)
- Quality of life
- Short-term and long-term toxicity
- Cost-effectiveness
- Local/regional or distant disease control
- Response rates
- Accuracy of diagnostic tests

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases
Searches of Patient Registry Data
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

For the 1997 guideline, pertinent information from the published literature as of April 1997 was retrieved and reviewed for the creation of these guidelines. Searches were done of MEDLINE (National Library of Medicine, Bethesda, MD) and other data bases for pertinent articles. Directed searches were made of the primary articles. In addition, certain authors/investigators were contacted to obtain more recent and, in some cases, unpublished information. Selected data from the Eastern Cooperative Oncology Group (ECOG) NSCLC data base were considered to determine historical experience with single agents and with second-line therapies, and for updated results of ongoing trials.

For the 2003 update, pertinent information published from 1996 through March 2003 was reviewed. The MEDLINE database (1996 through October 2002; National Library of Medicine, Bethesda, MD) was searched to identify relevant information from the published literature for this update. A series of searches was conducted using the medical subject headings, "carcinoma, non–small-cell lung," "diagnostic imaging," "neoplasm staging," "mediastinoscopy," "bone neoplasms," "brain neoplasms," "liver neoplasms," "adrenal gland neoplasms," "non–small-cell lung cancer," "radionuclide imaging," "bisphosphonates," "radiotherapy," "smoking," "chemoprevention," and the text words "chemotherapy," "bone scan," "PET," and "zoledronic acid." These terms were combined with the study design–related subject headings or text words "meta-analysis" and "randomized controlled trial." Search results were limited to human studies and English-language articles. The Cochrane Library was searched in October 2002 using the phrase "lung cancer." Directed searches based on the bibliographies of primary articles were also performed. Randomized trials published in the literature since October 2002, as well as data presented at American Society of Clinical Oncology Annual Meetings, were added to the evidence for these guidelines at the discretion of members of the Expert Panel.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The entire update committee met once to discuss strategy and assign responsibilities for the update. A writing committee subsequently met to further review the literature searches, collate different sections of the update, and refine the manuscript.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Fluorodeoxyglucose positron emission tomography (FDG-PET)

Decision analyses demonstrate that FDG-PET may reduce the overall costs of medical care by identifying patients with falsely negative computed tomography (CT) scans in the mediastinum or otherwise undetected sites of metastases. However, these studies concluded that the money saved by forgoing mediastinoscopy in FDG-PET–positive mediastinal lesions was not justified due to the unacceptably high number of false-positive results.

Evaluation of Adrenal Masses

A decision analysis model has been used to study the most cost-effective way to evaluate an adrenal mass in patients with non-small-cell lung cancer (NSCLC). Sequences which moved straight to needle biopsy after only one negative radiologic test were not cost-effective in this analysis, with unenhanced CT, chemical shift magnetic resonance imaging, and CT-guided biopsy being the diagnostic options. FDG-PET was not included as a diagnostic option. Further validation of such an approach is required before incorporation into practice is recommended.

Chemotherapy

Cost analyses of chemotherapy continue to support the cost-effectiveness of combination and single-agent chemotherapy for patients with metastatic disease compared with best supportive care. Given the relative equivalence in efficacy and toxicity of the platinum-based doublets, economic analyses have been performed in an attempt to identify the most cost-effective chemotherapy regimens.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

For the 1997 guideline, an expert in cancer quality of life and several practitioners in both academic and community settings who had not been directly involved in development of the guidelines were asked to assess the clarity and utility of the document. The content of the guidelines and the manuscript were reviewed and approved by the American Society of Clinical Oncology's (ASCO's) Health Services Research Committee and by the ASCO Board of Directors before dissemination.

For the 2003 update, a draft update was circulated to the full Expert Panel for review and approval. The final document was also reviewed by ASCO´s Health Services Research Committee and the ASCO Board of Directors.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): The American Society of Clinical Oncology (ASCO) has updated its 1997 recommendations on the treatment of unresectable non-small-cell lung cancer. Each recommendation from the 1997 guideline is listed below and is followed by an updated (2003) recommendation, if applicable. "No change" is indicated if a particular recommendation has not been revised.

Diagnostic Evaluation of Patients with Advanced Lung Cancer

Staging Locoregional Disease

1997 Recommendations

1. A chest x-ray and chest computed tomography (CT) scan with infusion of contrast material are recommended to stage locoregional disease. The CT scan should extend inferiorly to include the liver and the adrenal glands.
2. For patients with clinically operable non-small-cell lung cancer (NSCLC), biopsy is recommended of mediastinal lymph nodes found on chest CT scan to be $\geq$1 cm in shortest transverse axis.

2003 Recommendations

1. A chest x-ray and chest CT scan with infusion of contrast material are recommended to stage locoregional disease. The CT scan should extend inferiorly to include the liver and adrenal glands. Assuming there is no evidence of distant metastatic disease on CT scan, fluorodeoxyglucose positron emission tomography (FDG-PET) scanning complements CT scan and is recommended.
2. For patients with clinically operable NSCLC, biopsy is recommended of mediastinal lymph nodes found on chest CT scan to be greater than 1.0 cm in shortest transverse axis, or positive on FDG-PET scanning. Negative FDG-PET scanning does not preclude biopsy of radiographically enlarged mediastinal lymph nodes.

Staging Distant Metastatic Disease

1997 Recommendations

1. Bone: A bone scan should be performed only in patients who complain of A) bone pain or B) chest pain, or who have C) an elevated serum calcium level or D) an elevated serum alkaline phosphatase level.
2. Brain: Head CT or magnetic resonance imaging (MRI) of the brain with and without infusion of contrast material should be obtained only in patients who have signs or symptoms of central nervous system (CNS) disease.
3. Adrenal: The finding of an isolated adrenal mass on ultrasonographic or CT scan requires biopsy to rule out metastatic disease if the patient is otherwise considered to be potentially resectable.
4. Liver: The finding of an isolated liver mass on ultrasonographic or CT scan requires biopsy to rule out metastatic disease if the patient is otherwise considered to be potentially resectable.

2003 Recommendations

1. General: For the staging of distant metastatic disease, an FDG-PET scan is recommended when there is no evidence of distant metastatic disease on CT scan of the chest.
2. Bone: A bone scan is optional in patients who have evidence of bone metastases on FDG-PET scanning, unless there are suspicious symptoms in regions not imaged by FDG-PET. In patients with a surgically resectable primary lung lesion, bone lesions discovered on bone scan or FDG-PET require histologic confirmation, or corroboration by additional radiologic testing (x-ray, CT, and/or MRI).

3. Brain: Head CT or MRI brain imaging with and without infusion of contrast material is recommended in patients who have signs or symptoms of central nervous system disease, as well as asymptomatic patients with stage III disease who are being considered for aggressive local therapy (chest surgery or radiation).
4. Adrenal: The finding of an isolated adrenal mass on ultrasonography, CT scan, or FDG-PET scan requires biopsy to rule out metastatic disease if the patient is otherwise considered to be potentially resectable.
5. Liver: The finding of an isolated liver mass on ultrasonography, CT scan, or FDG-PET scan requires biopsy to rule out metastatic disease if the patient is otherwise considered to be potentially resectable.

Treatment

The Role of Chemotherapy

1997 Recommendations

1. Outcome
    - Unresectable stage III NSCLC: Chemotherapy in association with definitive thoracic irradiation is appropriate for selected patients with unresectable, locally advanced NSCLC.
    - Stage IV NSCLC: Chemotherapy is appropriate for selected patients with stage IV NSCLC.
2. Patient Selection
    - Unresectable stage III NSCLC: In unresectable stage III disease, chemotherapy plus radiotherapy prolongs survival and is most appropriate for individuals with good performance status (Eastern Cooperative Oncology Group [ECOG]/Zubrod performance status 0 or 1, and possibly 2) compared with radiation alone.
    - Stage IV NSCLC: In stage IV disease, chemotherapy prolongs survival and is most appropriate for individuals with good performance status (ECOG/Zubrod 0 or 1, and possibly 2)
3. Selection of Drugs

    Chemotherapy given to NSCLC patients should be a platinum-based combination regimen.

4. Duration of Therapy
    - Unresectable Stage III NSCLC
        - In patients with unresectable stage III NSCLC who are candidates for combined chemotherapy and radiation, the duration of chemotherapy should be two to eight cycles.
        - In the absence of compelling data, the Panel consensus is that in patients with unresectable stage III NSCLC who are candidates for combined chemotherapy and radiation, the duration of chemotherapy should be no more than eight cycles.
    - Stage IV NSCLC: In the absence of compelling data, the Panel consensus is that chemotherapy should be administered for no more than eight cycles in patients with stage IV NSCLC.
5. Timing of Treatment

- Unresectable stage III NSCLC: In patients with unresectable stage III disease, chemotherapy may best be started soon after the diagnosis of unresectable NSCLC has been made. Delaying chemotherapy until performance status worsens or weight loss develops may negate the survival benefits of treatment.
- Stage IV NSCLC: In patients with stage IV disease, if chemotherapy is to be given it should be initiated while the patient still has good performance status.

6. Second-Line Therapy

   There is no current evidence that either confirms or refutes that second-line chemotherapy improves survival in nonresponding or progressing patients with advanced NSCLC. Second-line treatment may be appropriate for good performance status patients for whom an investigational protocol is not available or desired, or for patients who respond to initial chemotherapy and then experience a long progression-free interval off treatment.

7. Role of Investigational Agents/Options

   Initial treatment with an investigational agent or regimen is appropriate for selected patients with stage IV NSCLC, provided that patients are crossed over to an active treatment regimen if they have not responded after two cycles of therapy.

8. Histology

   NSCLC histology is not an important prognostic factor in patients with advanced, unresectable disease. The use of newer, putative prognostic factors such as RAS mutations or p53 mutations is investigational and should not be used in clinical decision-making.

2003 Recommendations

1. Outcome
   - Unresectable stage III NSCLC: No change
   - Stage IV NSCLC: No change
2. Patient Selection
   - Unresectable stage III NSCLC: No change
   - Stage IV NSCLC: No change
3. Selection of Drugs
   - Unresectable stage III NSCLC: No change
   - Stage IV NSCLC: First-line chemotherapy given to patients with advanced NSCLC should be a two-drug combination regimen. Non–platinum-containing chemotherapy regimens may be used as alternatives to platinum-based regimens in the first line. For elderly patients or patients with ECOG/Zubrod performance status 2, available data support the use of single-agent chemotherapy.
4. Duration of Therapy
   - Unresectable stage III NSCLC:
     - In patients with unresectable stage III NSCLC who are candidates for combined chemotherapy and radiation, the

duration of chemotherapy should be two to four cycles of initial, platinum-based chemotherapy.
        - In the absence of compelling data, the Panel consensus is that in patients with unresectable stage III NSCLC who are candidates for combined chemotherapy and radiation, the duration of initial platinum-based chemotherapy should be no more than four cycles.
    - Stage IV NSCLC: In patients with stage IV NSCLC, first-line chemotherapy should be stopped at four cycles in patients who are not responding to treatment. The Panel consensus is that first-line chemotherapy should be administered for no more than six cycles in patients with stage IV NSCLC.
5. Timing of Treatment
    - Unresectable stage III NSCLC: No change
    - Stage IV NSCLC: No change
6. Second-Line Therapy

    Docetaxel is recommended as second-line therapy for patients with locally advanced or metastatic NSCLC with adequate performance status who have progressed on first-line, platinum–based therapy. Gefitinib is recommended for the treatment of patients with locally advanced or metastatic non–small-cell lung cancer after failure of both platinum-based and docetaxel chemotherapies.

7. Role of Investigational Agents/Options

    No change

8. Histology

    No change

Radiotherapy

1997 Recommendations

1. Radiation for Locally Advanced Unresectable NSCLC

    Radiation therapy should be included as part of treatment for selected patients with unresectable locally advanced NSCLC.

2. Patient Selection

    Candidates for definitive thoracic radiotherapy with curative intent should have performance status 0, 1, or possibly 2, adequate pulmonary function, and disease confined to the thorax. Patients with malignant pleural effusions and those with distant metastatic disease are not appropriate for definitive thoracic radiotherapy.

3. Dose and Fractionation

Definitive-dose thoracic radiotherapy should be no less than the biologic equivalent of 60 Gy, in 1.8-Gy to 2.0-Gy fractions.

4. Local- and Distant-Site Palliative Effects of External-Beam Radiation

   Local symptoms from primary or metastatic NSCLC can be relieved by a variety of doses and fractionations of external-beam radiotherapy. In appropriately selected patients, hypofractionated palliative radiotherapy (of one to five fractions instead of 10) may provide symptomatic relief with acceptable toxicity in a more time efficient and less costly manner.

2003 Recommendations

1. Radiation for Locally Advanced Unresectable NSCLC

   No change

2. Patient Selection

   No change

3. Dose and Fractionation

   No change

4. Local- and Distant-Site Palliative Effects of External-Beam Radiation

   No change

Surgery

1997 Recommendations

1. Role of Resection for Distant Metastases

   In patients with controlled disease outside of the brain who have an isolated cerebral metastasis in a resectable area, resection followed by whole-brain radiotherapy (WBRT) is superior to WBRT alone.

2003 Recommendations

1. Role of Resection for Distant Metastases
   - In patients with controlled disease outside of the brain who have an isolated cerebral metastasis in a resectable area, resection followed by WBRT is superior to WBRT alone.
   - While feasible in selected patients, there is insufficient evidence to support routine resection of solitary adrenal metastases.

<u>Surveillance and Follow-up Care for Patients with Advanced Lung Cancer</u>

1997 Recommendations

1. History and Physical Examination

   For patients treated with curative intent, in the absence of symptoms, a history and physical examination should be performed every 3 months during the first 2 years, every 6 months thereafter through year 5, and yearly thereafter.

2. Chest Radiographs

   For patients treated with curative intent, there is no clear role for routine studies in asymptomatic patients and for those in whom no interventions are planned. A yearly chest x-ray to evaluate for potentially curable second primary cancers may be reasonable.

3. Other Diagnostic Studies

   There is no role for routine studies in most asymptomatic patients and those patients not undergoing therapeutic interventions. CT scan of the chest/abdomen; CT/MRI of the brain; bone scan; bronchoscopy; complete blood cell count (CBC); and routine chemistries, including liver function tests, should only be performed as indicated by the patient's symptoms.

2003 Recommendations

1. History and Physical Examination

   No change

2. Chest Radiographs

   For patients treated with curative intent, there is no clear role for routine studies in asymptomatic patients and for those in whom no interventions are planned.

3. Other Diagnostic Studies
   - There is no role for routine studies in most asymptomatic patients and those patients not undergoing therapeutic interventions. CT scan of the chest/abdomen; CT scan/MRI of the brain; FDG-PET scan; bone scan; bronchoscopy; CBC; and routine chemistries, including liver function tests, should only be performed as indicated by the patient's symptoms.
   - Low-dose helical chest CT is more sensitive than chest x-ray for the identification of second primary cancers, but at this time remains investigational as part of the routine follow-up of patients with a history of unresectable NSCLC.

<u>Lifestyle Changes to Prevent Recurrent Lung Cancer</u>

1997 Recommendations

1. Smoking Cessation

   Smoking cessation, never initiating smoking, and avoidance of occupational and environmental exposure to carcinogenic substances are recommended as effective interventions to reduce the risk of second primary NSCLC in curatively treated patients. In patients with distant metastatic NSCLC, the outlook is poor and smoking cessation has little effect on overall prognosis but may improve respiratory symptoms.

2. Chemopreventive Agents

   The use of antioxidants and/or chemopreventive agents for NSCLC is investigational and their clinical use off-study is not recommended.

2003 Recommendations

1. Smoking Cessation

   Smoking cessation, never initiating smoking, and avoidance of occupational and environmental exposure to carcinogenic substances are recommended as effective interventions to reduce the risk of second primary NSCLC in curatively treated patients. Of these interventions, the first two have the largest public health impact. In patients with distant metastatic NSCLC, the outlook is poor, and smoking cessation has little effect on overall prognosis but may improve respiratory symptoms.

2. Chemopreventive Agents

   No change

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type and grade of evidence is identified and graded for each recommendation (see Major Recommendations).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Prolonged survival
- Higher probability of achieving an objective response
- Lessened likelihood of experiencing treatment-related toxicity
- Symptom palliation

POTENTIAL HARMS

- Harms considered were inappropriate disease management and excess cost without definable benefit.
- Chemotherapy is associated with short- and long-term toxicity.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The American Society of Clinical Oncology (ASCO) considers adherence to these guidelines to be voluntary. The ultimate determination regarding their application is to be made by the physician in light of each patient's individual circumstances. In addition, these guidelines describe evaluations and administration of therapies in clinical practice; they cannot be assumed to apply to interventions performed in the context of clinical trials, given that such clinical studies are designed to test innovative management strategies in a disease for which better treatment is sorely needed. However, by reviewing and synthesizing the latest literature, this practice guideline serves to identify questions for further research and the settings in which investigational therapy should be considered.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

End of Life Care
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Pfister DG, Johnson DH, Azzoli CG, Sause W, Smith TJ, Baker S Jr, Olak J, Stover D, Strawn JR, Turrisi AT, Somerfield MR. American Society of Clinical Oncology treatment of unresectable non-small-cell lung cancer guideline: update 2003. J Clin Oncol 2004 Jan 15;22(2):330-53. [293 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1997 May (revised 2004 Jan 15)

GUIDELINE DEVELOPER(S)

American Society of Clinical Oncology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Society of Clinical Oncology (ASCO)

GUIDELINE COMMITTEE

American Society of Clinical Oncology (ASCO) Non-Small-Cell Lung Cancer Expert Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

1997 Version of Guideline

The Panel was composed of experts in clinical medicine, clinical research, outcomes/health services research, and related disciplines (medical decision-making, health economics, and quality of life) and medical ethics, with a focus on expertise in NSCLC. A patient representative was also included on the Panel. The clinical experts represented all relevant medical disciplines, including medical oncology, radiation oncology, thoracic surgery, and pulmonology. Both academic and community practitioners were included.

Panel Members: Daniel C. Ihde, MD, Co-Chair, Washington University School of Medicine, St Louis, MO; David G. Pfister, MD, Co-Chair, Memorial Sloan-Kettering Cancer Center, New York, NY; Sherman Baker, Jr, MD, Lahey Hitchcock Clinic, Nashua, NH; Albert Bernath, MD, Geisinger Medical Center, Danville, PA; Frank J. Brescia, MD, Emory University School of Medicine, Atlanta, GA; Ed Fontenot, Patient Representative; Mark R. Green, MD, Hollings Cancer Center, Charleston, SC; David H. Johnson, MD, Vanderbilt University Medical School, Nashville, TN; Jemi Olak, MD, University of Chicago Medical Center, Chicago, IL; William Sause, MD, LDS Hospital, Salt Lake City, UT; Thomas J. Smith, MD, Chairman, ASCO Health Services Research Committee; Diane Stover, MD, Memorial Sloan Kettering Cancer Center, New York, NY; Andrew T. Turrisi III, MD, Medical University of South Carolina, Charleston, SC; Paul Waters, MD, UCLA Center for Health Sciences, Los Angeles, CA; Rodger J. Winn, MD, M.D. Anderson Cancer Center, Houston, TX

2004 Version of Guideline

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The following authors or their immediate family members have indicated a financial interest. No conflict exists for drug or devices used in a study if they are not being evaluated as part of the investigation. Acted as a consultant within the last 2 years: Andrew T. Turrisi, AstraZeneca.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Society of Clinical Oncology (ASCO) Web site:

- HTML Format
- Portable Document Format (PDF)

Print copies: Available from American Society of Clinical Oncology, Health Services Research, 1900 Duke Street, Suite 200, Alexandria, VA 22314.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

- Advanced lung cancer treatment. Alexandria (VA): American Society of Clinical Oncology; 2003. 16 p.

Electronic copies: Available from the American Society for Clinical Oncology (ASCO) Web site.

NGC STATUS

This summary was completed by ECRI on September 1, 1998. It was verified by the guideline developer on December 1, 1998. This guideline was updated by ECRI on February 16, 2004. The updated information was verified by the guideline developer on February 26, 2004.

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